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TECHNOLOGY CENTER R3700

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application Of:

Archie Woodworth et al.

For: POLYMERIC SYRINGE  
BODY AND STOPPER

Serial No.: 09/801,864

Filed: March 28, 2001

Examiner: Not-yet-assigned

Art Unit: 3721

Conf. No. 6736

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Robert J. Buccieri
REPLY TO NOTICE UNDER 37 CFR 1.251

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Dear Sir:

This is in response to a Notice Under 37 CFR 1.251 mailed May 7, 2003, with a shortened three month response date. Hence, this Response is timely filed.

Applicant was requested to provide and hereby does enclose the following:


- (1) a complete and accurate copy of Applicant's record of all of the correspondence between the Patent Office and Applicant for the above-identified patent application (excepting copies of U.S. Patent documents); and
- (2) a list of such correspondence.

Applicant hereby states that the enclosed copy is a complete and accurate copy of Applicant's record of all of the correspondence between the Office and Applicant; and Applicant is not aware of any correspondence between the Office and Applicant that is not among Applicant's records.

Respectfully submitted,  
BELL, BOYD & LLOYD LLC

Date: June 18, 2003

BY

  
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App. Dkt. No.: CLS-5772  
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- 3 -

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JUN 23 2003 PATENT  
Serial No. 09/801,864  
TECHNOLOGY CENTER R3700

DATE	DESCRIPTION OF DOCUMENT	TAB #
3/8/2001	Postcard; Express Mail Label; Express Mail Cover Sheet (1 pg.); Application Transmittal Letter (2 pgs.); Specification (23 pgs.); Informal Drawings (5 sheets, FIGS. 1-5).	1
6/7/2001	Postcard; Information Disclosure Statement (1 pg.); PTO-1449 (7 pgs.) citing 155 US Patents (copies not included) and 27 foreign Patents.	2
7/5/2001	Filing Receipt	3
7/5/2001	Notice to File Missing Parts – Response due 9/5/2001	4
7/26/2001	Postcard; Supplemental IDS (2 pgs.); Form PTO-1449 (1 pg.); 3 US Patents.	5
12/4/2001	Postcard; Response to Notice to File Missing Parts (2 pgs.); Petition for 3 month Extension of Time (1 pg.); Notice to File Missing Parts (Response Copy – 1 pg.); Executed Declaration and Power of Attorney (6 pgs.); Check for \$1,476; Check for \$920.	6
2/26/2002	Postcard; Supplemental IDS (1 pg.); Form PTO-1449 (2 pgs.); 19 US Patents and 17 foreign patents.	7
5/3/2002	Updated Filing Receipt	8
10/3/2002	Notice of Publication of Application	9
5/7/2003	Notice Under 37 CFR 1.251 – Response due 8/7/2003	10

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Re: Polymeric Syringe and Stopper

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Enclosures:

- Patent Application Transmittal (in duplicate);
- Specification, claims and abstract;
- 5 Sheets of informal drawings; and
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PATENT TRADEMARK OFFICE

Attorney Docket No. 1417Y P 552

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re U.S. Utility Patent Application of:	)
Archie Woodworth      Jim Kamienski	)
John Falzone            Peggy Barnato	)
John Darvasi            Bob Gliniecki	)
Amy Gillam	)
	)
	)
For: Polymeric Syringe and Stopper	)
	)
Mailed: March 8, 2001	)

**PATENT APPLICATION TRANSMITTAL**

Box Patent Application  
Fee  
Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Enclosed are the following documents:

- X   Specification, Claims and Abstract
- X     5   Sheets of Informal Drawings (Figures 1-5).
- Declaration and Power of Attorney.



26966

PATENT TRADEMARK OFFICE

Attorney Docket No. 1417Y P 552  
Application Title: Polymeric Syringe and Stopper  
Page 2

The filing fee has been calculated as shown below:

For:	No. Filed	No. Extra	Small Entity		or	Other Than A Small Entity	
			Rate	Fee		Rate	Fee
Basic Fee				\$355	or		\$710
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Indep. Claims	7 - 3 =	4	x49 =	\$	or	x 80 =	\$320
<input type="checkbox"/> First Presentation of Multiple Dependent Claim			x135 =	\$0	or	x270 =	\$0
			Total	\$	or	Total	\$1300

Respectfully submitted,

Date: March 8, 2001

By: Peter M. Klobuchar

Peter M. Klobuchar, Registration No. 43,722  
Wallenstein & Wagner, Ltd.  
311 S. Wacker Drive, 53rd Floor  
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**CERTIFICATION UNDER 37 C.F.R. § 1.10**

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Gerianne M. Flannery  
Gerianne M. Flannery 117548.1



26966

PATENT TRADEMARK OFFICE

In Re Utility Application Of:      Woodworth, et al.  
For:      Polymeric Syringe and Stopper  
W&W File No.      1417Y P 552

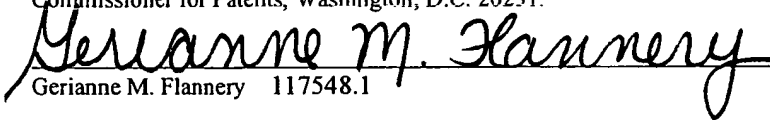
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Patent Application Transmittal (in duplicate).  
Specification, Claims and Abstract.  
5 Sheets Informal Drawings (Figs. 1-5).

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Gerianne M. Flannery 117548.1



26966

PATENT TRADEMARK OFFICE

W&W Ref. No. 1417Y P 552  
(117626.1)

PATENT

## POLYMERIC SYRINGE BODY AND STOPPER

### DESCRIPTION

#### Technical Field

The present invention relates generally to a polymeric syringe body and stopper, and more specifically to a syringe body produced from a cyclic olefin copolymer in combination with an elastomeric stopper.

5

#### Background Prior Art

Typically, glass syringe bodies are manufactured by producing the syringe body in a production plant. The syringe bodies are packaged and shipped to a pharmaceutical plant where they are unpackaged, filled, sealed tightly, and sterilized.

10 The syringe bodies are then repackaged and ready to be delivered to the end user. This process is inefficient and costly.

Recently, syringe bodies have been manufactured from polymeric resins. The polymeric syringe bodies replaced glass syringe bodies which were costly to produce and caused difficulties during the manufacturing process because the glass would chip, crack, or break. The broken glass particles would not only become hazards to workers and manufacturing equipment, but would also become sealed within the glass syringe body causing a potential health hazard to a downstream patient.

U.S. Patent No. 6,065,270 (the '270 patent), issued to Reinhard et al. and assigned to Schott Glaswerke of Germany, describes a method of producing a  
20 prefilled, sterile syringe body from a cyclic olefin copolymer (COC) resin. A COC polymer is useful in the manufacture of syringe bodies because it is generally clear and transparent. COC resins are, for example, disclosed in U.S. Patent No. 5,610,253 which is issued to Hatke et al. and assigned to Hoechst Akteiengesellschaft of Germany.

25 The '270 patent includes a method of manufacturing a filled plastic syringe body for medical purposes. The syringe body comprises a barrel having a rear end which is open and an outlet end with a head molded thereon and designed to accommodate an injection element, a plunger stopper for insertion into the rear end of the barrel to seal it, and an element for sealing the head. The method of

manufacturing the syringe body includes the steps of: (1) forming the syringe body by injection molding a material into a core in a cavity of an injection mold, the mold having shape and preset inside dimensions; (2) opening and mold and removing the formed syringe body, said body having an initial temperature; (3) sealing one end of the barrel of the plastic syringe body; (4) siliconizing an inside wall surface of the barrel of the plastic syringe body immediately after the body is formed and while the body remains substantially at said initial temperature; (5) filling the plastic syringe body through the other end of the barrel of the plastic syringe body; and (6) sealing the other end of the barrel of the plastic syringe body, wherein the method is carried out in a controlled environment within a single continuous manufacturing line.

According to the method of the '270 patent, the sterilization step is applied to the filled and completely sealed ready-to-use syringe body. Historically, sterilization of finished syringe components (barrel, plunger, and tip cap) has been conducted using ethylene oxide, moist-heat or gamma irradiation.

#### 15 **Summary of the Invention**

Other features and advantages of the invention will be apparent from the following specification taken in conjunction with the following drawings.

The present invention provides a flowable materials container. The container has a body of a cyclic olefin containing polymer or a bridged polycyclic olefin containing polymer, the body defining a chamber to contain flowable materials, the chamber having an opening; an elastomeric component attached to the body and providing a seal of the chamber; and wherein the body when filled with 1 ml of water suitable for injection and sealed with the elastomeric component and stored for 3 months generates less than 4 ppm of chlorides in the water.

25 The present invention further provides a flowable materials container having body of a homopolymer, copolymer or terpolymer of norbornene, the body defining a chamber to contain flowable materials, the chamber having an opening; and an elastomeric component providing a seal of the opening and the component being a butyl rubber.

30 The present invention further provides a syringe having a syringe body of a norbornene and ethylene copolymer, the body defining a chamber for containing water and having an opening; and a plunger seal of a halobutyl based elastomer sealing the opening.

The present invention further provides a syringe body of a norbornene and ethylene copolymer, the body defining a chamber for containing water and having an opening; a plunger seal of a halobutyl based elastomer sealing the opening; and wherein the syringe meets all requirements of the United States Pharmacopoeia for sterile water for injection.

The present invention further provides a sterile water for injection syringe having a syringe body of a norbornene and ethylene copolymer, the body defining a chamber containing water and having an opening; a plunger seal of a halobutyl-based elastomer forming a fluid tight seal of the opening; and wherein the syringe meets all requirements of the United States Pharmacopoeia for sterile water for injection.

The present invention further provides a method for filling a syringe including the steps of: (1) providing a syringe body of a norbornene and ethylene copolymer and having an opening; (2) sterilizing the syringe body to define a sterilized syringe body; (3) transferring the sterilized syringe body to a sterile environment while maintaining the sterility of the sterilized syringe body; filling the sterilized syringe body with an appropriate quantity of sterile water for injection; (4) sealing the opening with an elastomeric component of a halobutyl based elastomer to define a sterile water for injection syringe; and wherein the sterile water for injection syringe meets the requirements of the United States Pharmacopoeia for sterile water for injection.

The present invention further provides a method for filling a syringe including the steps of: (1) providing a syringe body of a norbornene and ethylene copolymer and having an opening; (2) sterilizing the syringe body to define a sterilized syringe body; (3) transferring the sterilized syringe body to a sterile environment while maintaining the sterility of the sterilized syringe body; (4) immediately filling the sterilized syringe body with an appropriate quantity of sterile water for injection; (5) sealing the opening with an elastomeric component of a halobutyl-based elastomer to define a sterile water for injection syringe; and (6) wherein the sterile water for injection syringe meets the requirements of the United States Pharmacopoeia for sterile water for injection.

#### **Brief Description of the Drawings**

Figure 1 is a view of a syringe body;

Figure 2 is a flowchart of the method of the present invention;

Figure 3 is a flowchart of a second embodiment of the method of the present invention;

Figure 4 is a flowchart of a third embodiment of the method of the present invention; and

Figure 5 is a plot showing the trend in pH of the sterile water for injection within a syringe of the present invention days to fill.

5

### **Detailed Description**

While this invention is susceptible of embodiments in many different forms, there are shown in the drawings and will herein be described in detail, preferred embodiments of the invention with the understanding that the present disclosures are

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10 to be considered as exemplifications of the principles of the invention and are not intended to limit the broad aspects of the invention to the embodiments illustrated.

The present invention is directed to a method for continuously producing sterile prefilled container, such as a medical vial but preferably a prefilled, sterile, polymeric syringe body. Throughout this specification, syringe bodies are used as an

15 illustrative example of the type of container provided; however, it should be understood that method of the present invention can be applied to any containers, vials, other types of storage vessels, or IV kits without departing from the spirit of the invention. The containers of the present invention can be used to contain flowable materials. A flowable material is one that can flow under the force of gravity or when

20 entrained in a pressurized fluid stream such as air. The container further includes components, such as cartridges, of a needlefree injection system such as those disclosed in representative U.S. Patents 5,399,163, 5,891,086, 6,096,002 and PCT International Publication No. WO 00/35520, each of which is incorporated herein by reference and made a part hereof.

25 Referring to Figure 1, the syringe bodies 1 are of the type having at least one interior chamber 2 defined by an inner cylindrical sidewall 3, a tip end 4 having an opening adapted for receiving an injection needle or the like and a larger open end 5 for receiving a plunger arm 6a having a plunger seal 6b at a distal end of the plunger arm for activating a flow of a fluid substance outwardly from the chamber 2 through

30 the tip end 4. The tip ends 4 are typically equipped with a tip cap 7. Such syringe bodies 1 are commonly used in medical applications.

#### **I. Syringe bodies**

The syringe bodies 1 can be produced from glass or any suitable polymer, but are preferably produced from cyclic olefin containing polymers or bridged polycyclic hydrocarbon containing polymers. These polymers, in some instances, shall be collectively referred to as COCs.

5       The use of COC-based syringe bodies overcome many of the drawbacks associated with the use of glass syringe bodies. The biggest drawbacks of glass syringe bodies are in connection with the handling of the glass syringes. For instance, the glass syringes are often chipped, cracked, or broken during the manufacturing process. Glass particles may become trapped within the syringe bodies and  
10 subsequently sealed within the syringe barrel with the medical solution. This could be hazardous to a patient injected with the medical solution. Additionally, the glass particles could become a manufacturing hazard by causing injury to plant personnel or damage to expensive manufacturing equipment.

Suitable COC polymers include homopolymers, copolymers and terpolymers.  
15 obtained from cyclic olefin monomers and/or bridged polycyclic hydrocarbons as defined below.

Suitable cyclic olefin monomers are monocyclic compounds having from 5 to about 10 carbons in the ring. The cyclic olefins can be selected from the group consisting of substituted and unsubstituted cyclopentene, cyclopentadiene,  
20 cyclohexene, cyclohexadiene, cycloheptene, cycloheptadiene, cyclooctene, cyclooctadiene. Suitable substituents include lower alkyl, acrylate derivatives and the like.

Suitable bridged polycyclic hydrocarbon monomers have two or more rings and more preferably contain at least 7 carbons. The rings can be substituted or  
25 unsubstituted. Suitable substitutes include lower alkyl, aryl, aralkyl, vinyl, allyloxy, (meth) acryloxy and the like. The bridged polycyclic hydrocarbons are selected from the group consisting of those disclosed in the below incorporated patents and patent applications and in a most preferred form of the invention is norbornene.

Suitable homopolymer and copolymers of cyclic olefins and bridged polycyclic  
30 hydrocarbons and blends thereof can be found in U.S. Patent Nos. 5,218,049, 5,854,349, 5,863,986, 5,795,945, 5,792,824; EP 0 291,208, EP 0 283,164, EP 0 497,567 which are incorporated in their entirety herein by reference and made a part hereof. These homopolymers, copolymers and polymer blends may have a glass

transition temperature of greater than 50°C, more preferably from about 70°C to about 180°C, a density greater than 0.910 g/cc and more preferably from 0.910g/cc to about 1.3 g/cc and most preferably from 0.980 g/cc to about 1.3 g/cc and have from at least about 20 mole % of a cyclic aliphatic or a bridged polycyclic in the backbone of the polymer more preferably from about 30-65 mole % and most preferably from about 30-60 mole %.

Suitable comonomers for copolymers and terpolymers of the COCs include  $\alpha$ -olefins having from 2-10 carbons, aromatic hydrocarbons, other cyclic olefins and bridged polycyclic hydrocarbons.

10 The presently preferred COC is a norbornene and ethylene copolymer. These norbornene copolymers are described in detail in U.S. Patent Nos. 5,783,273, 5,744,664, 5,854,349, and 5,863,986. The norbornene ethylene copolymers preferably have from at least about 20 mole percent norbornene monomer and more preferably from about 20 mole percent to about 75 mole percent and most preferably from about 30 mole percent to about 60 mole percent norbornene monomer or any combination or subcombination of ranges therein. The norbornene ethylene copolymer should have a glass transition temperature of from about 70-180°C, more preferably from 70-130°C. The heat deflection temperature at 0.45 Mpa should be from about 70°C to about 200°C, more preferably from about 75°C to about 150°C and most preferably from about 76°C to about 149°C. Also, in a preferred form of the invention, the COC is capable of withstanding, without significant heat distortion, sterilization by an autoclave process at 121°C. Suitable copolymers are sold by Ticona under the tradename TOPAS under grades 6013, 6015 and 8007 (not autoclavable).

Other suitable COCs are sold by Nippon Zeon under the tradename ZEONEX and ZEONOR, by Daikyo Gomu Seiko under the tradename CZ resin, and by Mitsui Petrochemical Company under the tradename APEL.

It may also be desirable to have pendant groups associated with the COCs. The pendant groups are for compatibilizing the COCs with more polar polymers including amine, amide, imide, ester, carboxylic acid and other polar functional groups. Suitable pendant groups include aromatic hydrocarbons, carbon dioxide, monoethylenically unsaturated hydrocarbons, acrylonitriles, vinyl ethers, vinyl esters, vinylamides, vinyl ketones, vinyl halides, epoxides, cyclic esters and cyclic ethers.

The monethylenically unsaturated hydrocarbons include alkyl acrylates, and aryl acrylates. The cyclic ester includes maleic anhydride.

Polymer blends containing COCs have also been found to be suitable for fabricating syringe bodies 1. Suitable two-component blends of the present invention include as a first component a COC in an amount from about 1% to about 99% by weight of the blend, more preferably from about 30% to about 99%, and most preferably from about 35% to about 99% percent by weight of the blend, or any combination or subcombination or ranges therein. In a preferred form of the invention the first component has a glass transition temperature of from about 70°C to about 130°C and more preferably from about 70-110°C.

The blends further include a second component in an amount by weight of the blend of about 99% to about 1%, more preferably from about 70% to about 1% and most preferably from about 65% to about 1%. The second component is selected from the group consisting of homopolymers and copolymers of ethylene, propylene, butene, hexene, octene, nonene, decene and styrene. In a preferred form of the invention the second component is an ethylene and  $\alpha$ -olefin copolymer where the  $\alpha$ -olefin has from 3-10 carbons, and more preferably from 4-8 carbons. Most preferably the ethylene and  $\alpha$ -olefin copolymers are obtained using a metallocene catalyst or a single site catalyst. Suitable catalyst systems, among others, are those disclosed in U.S. Patent Nos. 5,783,638 and 5,272,236. Suitable ethylene and  $\alpha$ -olefin copolymers include those sold by Dow Chemical Company under the AFFINITY and ENGAGE tradenames, those sold by Exxon under the EXACT tradename and those sold by Phillips Chemical Company under the tradename MARLEX.

Suitable three-component blends include as a third component a COC selected from those COCs described above and different from the first component. In a preferred form of the invention the second COC will have a glass transition temperature of higher than about 120°C when the first COC has a glass transition temperature lower than about 120°C. In a preferred form of the invention, the third component is present in an amount by weight of from about 10-90% by weight of the blend and the first and second components should be present in a ratio of from about 2:1 to about 1:2 respectively of the first component to the second component. about 70-100°C.

In a preferred three-component blend, a second norbornene and ethylene copolymer is added to the two component norbornene-ethylene/ethylene 4-8 carbon  $\alpha$ -olefin blend. The second norbornene ethylene copolymer should have a norbornene monomer content of 30 mole percent or greater and more preferably from about 35-75 mole percent and a glass transition temperature of higher than 120°C when the first component has a glass transition temperature of lower than 120°C.

## II. Plunger seal, vial stoppers and other elastomeric components

The plunger seal 6b, vial stopper or other elastomeric component used in conjunction with the COCs set forth above are fabricated from a polymeric material and more preferably a polymeric material that will not generate unacceptable levels of halogens after processing, filling with sterile water for injection, sterilization and storage. More particularly, a syringe body or vial made from one of the COCs set forth above having been filled with 1 ml of sterile water for injection and stoppered with a plunger arm 6a having an elastomeric plunger seal 6b (or other type stopper or closure suitable for the corresponding flowable materials container) will generate less than about 4 ppm of chlorides after three months of storage, more preferably less than about 3 ppm and most preferably less than about 2 ppm of chlorides. In a preferred form of the invention the plunger seal 6b is essentially latex-free and even more preferably 100% latex-free.

In an even more preferred form of the invention the plunger seal 6b and COC body 1 shall meet all limitations set by the United States Pharmacopoeia (Monograph No. 24, effective as of filing this patent application) for sterile water for injection. The USP for sterile water for injection is incorporated herein by reference and made a part hereof. In particular, USP sterile water for injection specifies the following limitations on concentrations: pH shall be from 5.0-7.0, ammonia less than 0.3 mg/ml, chlorides less than 0.5 mg/ml and oxidizable substances less than 0.2 mmol. The USP further specifies the absence of the following components when measured in accordance with the USP: carbon dioxide, sulfates and calcium ions.

Suitable polymeric materials for elastomeric components include synthetic rubbers including styrene-butadiene copolymer, acrylonitrile-butadiene copolymer, neoprene, butyl rubber, polysulfide elastomer, urethane rubbers, stereo rubbers, ethylene-propylene elastomers. In a preferred form of the invention, the elastomeric component is a halogenated butyl rubber and more preferably a chlorobutyl-based

elastomer. A presently preferred chlorobutyl-based elastomeric formulation are sold by Stelmi under the trade name ULTRAPURE 6900 and 6901.

It has been further observed that the USP requirements for sterile water for injection are met when the containers of the present invention are prepared using the  
5 following methods.

### III. Method

Referring to Figures 2 through 4, embodiments of the method of the present invention are illustrated in flowchart format. These embodiments generally comprise the steps of producing a plurality of syringe bodies 10, transferring the syringe bodies  
10 to a sterilization station 30, sterilizing the syringe bodies 50, transferring the syringe bodies to a sterile environment 70, processing the syringe bodies within the sterile environment 90, transferring the syringe bodies to a packaging station 110, and packaging the syringe bodies 130.

The methods of producing the sterile prefilled syringe bodies as disclosed  
15 herein do not require human intervention. Thus, contamination from human contact is eliminated. To maximize manufacturing of the sterile prefilled syringe bodies dual first and second manufacturing lines may be operated. The second lines are designated by prime reference numerals.

Referring specifically to Figure 2, the producing the syringe bodies step 10 of  
20 this embodiment includes continuously producing a plurality of syringe bodies 12a and 12b. Preferably, the syringe bodies are injection molded from a COC defined above. Typically, the syringe bodies can be molded at a rate of 150 units per minute. Thus, in order to satisfy faster downline subprocesses, two separate 150 unit per minute molding stations 12a and 12b are provided. Once the syringe bodies are  
25 molded, they are transferred to a quality control station 14a and 14b where the syringe bodies are inspected and weighed. Syringe bodies which satisfy a predetermined specification are transferred to a tip cap station 16a and 16b where tip caps are added to each syringe body to effectively seal and close the tip end of the syringe body. Next, the interior of the syringe bodies are lubricated, preferably with silicone. The  
30 siliconizing can be carried out prior to the tip caps being added without departing from the spirit of the invention.

During the transferring the syringe bodies to a sterilization station step 30, the syringe bodies are transported along a conveyor to a sterilization station. This differs

from typical manufacturing methods wherein the syringe bodies are produced at separate location, pre-sterilized, placed in nest trays or tubs, wrapped, and transported to a second manufacturing location where the tubs are unwrapped and processed in a batch sterilization procedure.

5           The sterilization of the syringe bodies is carried out during the sterilizing the syringe bodies step 50. The sterilization station may include a terminal process performed within an autoclave or an irradiation process. If performed in an autoclave, the sterilization medium is typically steam. Gamma radiation is typically provided to sterilize the syringe bodies through irradiation. In the methods of the present

10           invention, however, electron beam (e-beam) irradiation is preferably provided to sterilize the syringe bodies. Biosterile of Fort Wayne, Indiana supplies an electron accelerator which is capable of sterilizing the syringe bodies. The electron accelerator is sold under the tradename SB5000-4. E-beam irradiation is preferable to steam because irradiation sterilization is faster; it saves manufacturing space; and steam  
15           creates waste and causes a material handling problem. E-beam irradiation is preferable over gamma radiation because e-beam irradiation is less damaging to the syringe bodies and it is faster. With e-beam irradiation, there is less coloration of the polymeric material; thus, the clinician's ability to inspect the syringe body and its contents is improved.

20           The e-beam dose delivered to the syringe bodies is preferably in the range of 10-50 kGy, or any range or combination of ranges therein, and more preferably 25 kGy at approximately 1MeV to 10 MeV, or any range or combination of ranges therein, but preferably less than or equal to 1 MeV. In studies of the effect e-beam irradiation has on final pH of the medical solutions within the prefilled syringe bodies (which will be  
25           described in more detail below), some syringe bodies were given doses greater than 40 kGy.

          The dosage may be delivered by a single beam; however, to deliver a uniform dosage to the syringe bodies, a dual beam system is preferred. The dual e-beam system minimizes dosage variation across the syringe bodies. Accordingly, it is  
30           further preferred to have an e-beam source located on opposing sides of the conveyor.

          Once individual syringe bodies are sterilized, they are sterile transferred to a sterile environment 70 to maintain the sterility of the syringe bodies. The sterile environment is generally a presterilized enclosure in which sterile operations take

place under sterile conditions, such as an enclosed isolator, class 100 environment, or other sterile environment. The e-beam sterilization station generates a curtain or field of electrons which provides a sterile ambient atmosphere prior to the syringe bodies entering an adjacent, enclosed, sterile environment or isolator. This is advantageous because the syringe bodies do not need to be wrapped or otherwise sealed to remain sterilized as they are transferred to the sterile environment. In other words, the syringe bodies enter the sterilization station and remain unwrapped and sterilized as they are transferred through the curtain of electrons to the sterile environment. Thus, less handling is required; there is less paper and/or wrapping waste; and it allows the process to proceed continuously because there is no delay for wrapping and unwrapping of the syringe bodies.

The next step, processing the syringe bodies within the sterile environment 90, includes at least three sub-steps, namely filling the syringe bodies with a sterile medical solution 96, transferring a sterile plunger for each syringe body into the sterile environment 98, and adding a plunger to an open end of each syringe body 100. The medical solution is generally introduced by a filler unit provided by Inova GmbH of Schwabisch Hall, Germany. The medical solution is introduced into the syringe bodies via the open end of the syringe bodies which is opposite the tip capped end, although the medical solution can also be introduced through the tip end without departing from the spirit of the invention.

The plungers are sterilized prior to being transferred into the isolator 98 and may be sterilized in any conventional manner but are preferably processed through the e-beam unit. Once filled with the medical solution, the step of inserting a plunger into the open end of each syringe body 100 is carried out. Once inserted within the open end of the syringe body, the plunger forms a seal with an inner sidewall of the syringe body wherein the medical solution is sealed within the syringe body. The inner sidewall of the syringe bodies have been previously siliconized so that the inner sidewall of the syringe bodies are lubricated, and the plungers will not become fused or adhered to the inner sidewalls. The plungers are automatically added to the syringe bodies as part of the Inova filler process.

The material used to produce the plungers must be compatible with the process. If a material oxidizes as a result of the e-beam irradiation, the oxidizing substances may leach into the contents of the syringe body. Therefore, the stopper is

preferably from an elastomeric material such as chlorobutyl rubber, such as Stelmi 6901.

The next step is transferring the syringe bodies to the packaging station 110 from the isolator. In this embodiment, syringe bodies are typically transferred along  
5 conveyor; however, any transfer mechanism, such as a manual procedure, a sequential loader, via transfer tubs, or the like, can be used without departing from the spirit of the invention.

This transfer step 110 includes the step of transferring the syringe bodies from the isolator 112 and may optionally include a post-fill sterilization step 114. In this  
10 optional sterilization step 114, the syringe bodies and the contents thereof are sterilized either by ultraviolet radiation or steam. The ultraviolet sterilization is performed in-line and takes seconds. Any number of ultraviolet techniques may be employed, such as UV-C (254 nm), medium pressure UV, or pulsed UV. Steam sterilization is performed off-line in an autoclave and generally takes hours.

15 Following the optional post-fill sterilization step, the syringe bodies are transferred from the optional sterilization station to the packaging station 116. During the packaging station step 130, a plunger rod is fixedly attached to the plunger, and the finished syringes are inspected, labeled, and packaged for shipment to an end user. It is contemplated that no human intervention is required to inspect, label, and package  
20 the syringe bodies.

Referring to Figure 3, a second method of the present invention is illustrated. This method is similar to the first method and also comprises the steps of producing a plurality of syringe bodies 10, transferring the syringe bodies to sterilization station 30, sterilizing the syringe bodies 50, sterile transferring the syringe bodies to a sterile  
25 environment 70, processing the syringe bodies within the sterile environment 90, transferring the syringe bodies to a packaging station 110, and packaging the syringe bodies 130.

In this embodiment, the producing the syringe bodies step 10 does not include the sub-step of adding a tip cap to each molded syringe body. Rather, the tip caps are  
30 added to the syringe bodies subsequent to sterilization.

Here, the processing the syringe bodies within the sterile environment 90 step at least includes the sub-steps of transferring a sterilized tip cap for each syringe body into the sterilized environment 92, adding a tip cap to an open tip of each syringe body

94, filling the syringe bodies with a medical solution 96, transferring a sterile plunger for each syringe body into the sterile environment 98, and adding the plunger to an open end of a syringe body 100.

5 The tip caps are sterilized prior to being sterile transferred into the isolator 92 and may be sterilized in any conventional manner but are preferably processed through the e-beam unit or, alternatively, through a separate dedicated e-beam unit.. The plungers are processed in a similar manner. The tip caps are preferably added to the open tips of the syringe bodies 94 prior to the syringe bodies being filled with the medical solution 96, and the plungers are preferably added after the syringe bodies  
10 have been filled. However, the plungers may be added to the syringe bodies prior to the filling step and the tip caps added to the syringe bodies subsequent to the filling step without departing from the spirit of the invention.

The remaining steps of this embodiment are identical to the first embodiment.

Referring to Figure 4, a third, preferred embodiment of the method of the  
15 present invention is illustrated. In this embodiment, syringe bodies are molded and placed in a transfer tray prior to being transferred to the remaining steps. Thus, rather than a line of syringe bodies being processed through the manufacturing process, a plurality of syringe bodies are transported in a transfer tray through the manufacturing process.

20 Like the first and second embodiments, this embodiment includes the steps of producing a plurality of syringe bodies 10, transferring the syringe bodies to a sterilization station 30, sterilizing the syringe bodies 50, sterile transferring the syringe bodies to a sterile environment 70, processing the syringe bodies within the sterile environment 90, transferring the syringe bodies to a packaging station 110, and  
25 packaging the syringe bodies 130.

Referring specifically to Figure 4, the producing the syringe bodies step 10 of this embodiment includes continuously producing a plurality of syringe bodies 12a and 12b. Once the syringe bodies are molded, they are transferred to a quality control station 14a and 14b where the syringe bodies are inspected and weighed. Syringe  
30 bodies which satisfy a predetermined specification are transferred to a tip cap station 16a and 16b where tip caps are added to each syringe body to effectively seal and close one end of the syringe body. Next, the interior of the syringe bodies are siliconized for lubrication and inserted into a nest located with a transfer tray or tub

18a and 18b. The syringe bodies can be siliconized prior to addition of the tip caps without departing from the spirit of the invention.

During the transferring the syringe bodies to a sterilization station step 30, the syringe bodies are transported within the nested transfer tray along a conveyor to a sterilization station. The sterilization of the syringe bodies is carried out during the  
5 sterilizing the syringe body step 50. Again, the sterilization station preferably includes e-beam irradiation. Here, however, the e-beam dose delivered to the syringe bodies must be modified to take into account the increased mass of the plurality of syringe  
bodies along with the nested transfer tray. Accordingly, the dose of sterilizing  
10 irradiation is preferably in the range of 10 to 50 kGy, 20 to 40 kGy, 15 to 25 kGy, or any range or combination of ranges therein, and more preferably 25 kGy at approximately 1 MeV to 10 MeV, more preferably less than or equal to 5 MeV, or any range or combination of ranges therein.

The remaining steps of this embodiment are identical to the first embodiment  
15 with the exception that syringe bodies are processed within the nested transfer trays or tubs rather than along the conveyor.

Generally, the sterilized prefilled syringes described herein are filled with a parenteral solution, preferably sterile water for injection. It is important that the pH of the sterile water for injection be controlled and kept within certain upper and lower  
20 limits. One advantage of the methods disclosed herein is the tight control of the pH of the water for injection which resulted from using a plastic syringe body sterilized by e-beam irradiation shortly before filling the syringe bodies with sterile water for injection.

Referring to Figure 5, the plot illustrates the trend in pH over days to fill.  
25 Namely, the pH tends to decrease over time. The following example illustrates an advantage of the present invention; i.e. that sterilization of plastic syringe bodies with e-beam irradiation improved the stability of the solution pH of the sterile water for injection held in the syringe bodies over equivalent gamma irradiation of the syringe bodies.

30 Syringe bodies were irradiated and aseptically filled within 5 days of e-beam irradiation sterilization. After 3 months in storage at 40 degrees Celsius, 1 mL syringe bodies filled with 1 mL of water which had been sterilized using gamma irradiation (>40 kGy) had a solution pH of 4.71. Meanwhile, syringe bodies stored for 3 months

at 40 degrees Celsius which had been sterilized using e-beam irradiation (>40 kGy) had a solution pH of 5.25. Thus, the pH of the sterile water for injection remained within the USP limits of 5.0-7.0 over this time period only for the e-beam irradiated plastic syringe bodies.

5 Lower doses of e-beam irradiation also maintained the solution pH of water-filled plastic syringes more effectively. Plastic syringe bodies irradiated with doses of e-beam from 20-40 kGy were filled with water within 5 days of sterilization and evaluated after storage. After 2 days storage at 70 degrees Celsius, which appears to approximate at least 2 years storage at 25 degrees Celsius, solution pH remained  
10 within USP limits and varied with e-beam dose. The pH of solution was 6.02 at 20 kGy, 5.43 at 30 kGy, and 5.15 at 40 kGy. After 3 months storage at 40 degrees Celsius, 1 mL water-filled syringe bodies yielded pH values of 5.53 at 20 kGy and 5.25 at 40 kGy e-beam irradiation.

The process of filling syringe bodies immediately (within 15 minutes of  
15 irradiation) after e-beam irradiation sterilization has been identified as a factor in maintaining the pH of sterile water for injection in small syringe volumes. Plastic syringe bodies were sterilized with e-beam irradiation at 25 kGy and filled with water at various time intervals after irradiation. The syringe bodies were then stored separately for 2 days at ambient temperature and 2 days at 70 degrees Celsius. The  
20 solution pH was tested after storage. The results indicated that the immediately filled syringe bodies had substantially higher solution pH than those filled 2 and 6 days after irradiation.

The study was repeated and the results were confirmed with both e-beam and gamma irradiated plungers; thus, predicting that product shelf-life for small volume  
25 sterile water for injection filled polymeric syringe bodies may be extended with respect to solution pH by filling the e-beam irradiated polymeric syringe bodies immediately; i.e. within 15 minutes after receiving the e-beam irradiation. It is believed that immediate filling quenches the free radicals formed on the surface of the syringe bodies during irradiation especially when the syringe bodies are produced  
30 from a material where ionizing radiation causes the formation of free radicals that could lead to pH changes in the parenteral solution. If a material oxidizes as a result of the e-beam irradiation, the oxidized substances may leach into the contents of the syringe over time. Also, hydrogen peroxide levels of the water have been measured

and shown to be quite low (<50 ppb). Therefore, by reducing the pH change caused by the plastic syringe body, the shelf-life of the product is extended.

The following table summarizes the results of the study:

**Table 1: Immediate Fill of SWFI after E-Beam Processing of Plastic Syringe**

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**Bodies**

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	Fill Timing	Ambient Control	Two Days 70°C Storage
E-beam Irradiated (25kGy) Plastic Syringe Bodies with E-beam Irradiated (25 kGy) Elastomeric Plungers	Filled Immediately with 1 mL	5.97	5.66
	Filled Immediately with 10 mL	5.70	5.54
	Filled with 10 mL 6 Days Post-Irradiation	5.56	5.15
E-beam Irradiated 1 mL (25kGy) Plastic Syringe Bodies with E-beam Irradiated (25kGy) Elastomeric Plungers	Filled Immediately	6.09	5.77
	Filled 2 Days Post-Irradiation	5.78	5.08
	Filled 6 Days Post-Irradiation	5.88	5.12
E-beam Irradiated 1 mL (25kGy) Plastic Syringe Bodies with Gamma Irradiated (25kGy) Elastomeric Plungers	Filled Immediately	6.13	6.05
	Filled 2 Days Post-Irradiation	5.76	5.12
	Filled 6 Days Post-Irradiation	6.00	5.02

It will be understood that the invention may be embodied in other specific forms without departing from the spirit or central characteristics thereof. The present embodiments, therefore, are to be considered in all respects as illustrative and not restrictive, and the invention is not to be limited to the details given herein.

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**CLAIMS**

What is claimed is:

1. A flowable materials container comprising:  
a body of a cyclic olefin containing polymer or a bridged polycyclic olefin  
5 containing polymer, the body defining a chamber to contain flowable materials, the  
chamber having an opening;  
an elastomeric component attached to the body and providing a seal of the  
chamber; and  
wherein the body when filled with 1 ml of water suitable for injection and sealed  
10 with the elastomeric component and stored for 3 months generates less than 4 ppm of  
chlorides in the water.
2. The container of claim 1 wherein the body is a syringe body.
- 15 3. The container of claim 2 wherein the elastomeric component is a plunger seal.
4. The container of claim 1 wherein the elastomeric component is a synthetic  
rubber.
- 20 5. The container of claim 4 wherein the synthetic rubber is selected from the  
group consisting of styrene-butadiene copolymers, acrylonitrile-butadiene copolymers,  
neoprenes, butyl rubbers, polysulfide elastomers, urethane rubbers, stereo rubbers,  
ethylene-propylene elastomers.
- 25 6. The container of claim 5 wherein the synthetic rubber has halogen  
substitutents.
7. The container of claim 6 wherein the synthetic rubber is a halogenated butyl  
rubber.
- 30 8. The container of claim 7 wherein the synthetic rubber is a chlorobutyl-based  
elastomer.

9. A flowable materials container comprising:  
a body of a homopolymer, copolymer or terpolymer of norbornene, the body defining a chamber to contain flowable materials, the chamber having an opening; and  
an elastomeric component providing a seal of the opening and the component  
5 being a butyl rubber.
10. The container of claim 9 wherein the body is a homopolymer of norbornene.
- 
11. The container of claim 9 wherein the body is a copolymer of norbornene.
12. The container of claim 11 wherein the copolymer of norbornene has a comonomer selected from the group consisting of  $\alpha$ -olefins having from 2-10 carbons, aromatic hydrocarbons, cyclic olefins and bridged polycyclic olefins.
13. The container of claim 12 wherein the comonomer is ethylene.
14. The container of claim 9 wherein the butyl rubber is halogenated.
15. The container of claim 14 wherein the component is a chlorobutyl elastomer.
16. The container of claim 15 wherein the component is essentially latex free.
17. The container of claim 15 wherein the component is 100% latex free.
18. A syringe comprising:  
a syringe body of a norbornene and ethylene copolymer, the body defining a chamber for containing water and having an opening; and  
a plunger seal of a halobutyl based elastomer sealing the opening.
19. The syringe of claim 18 wherein the norbornene and ethylene copolymer has a heat deflection temperature at 0.45 Mpa from about 70°C to about 200°C.

20. The syringe of claim 18 wherein the norbornene and ethylene copolymer has a heat deflection temperature at 0.45 Mpa from about 75°C to about 150°.

21. The syringe of claim 18 wherein the norbornene and ethylene copolymer has  
5 a heat deflection temperature at 0.45 Mpa from about 76°C to about 149°C.

22. A syringe comprising:

a syringe body of a norbornene and ethylene copolymer, the body defining a  
chamber for containing water and having an opening;

10 a plunger seal of a halobutyl based elastomer sealing the opening; and  
wherein the syringe meets all requirements of the United States Pharmacopoeia  
for sterile water for injection.

23. A sterile water for injection syringe comprising:

15 a syringe body of a norbornene and ethylene copolymer, the body defining a  
chamber containing water and having an opening;

a plunger seal of a halobutyl based elastomer forming a fluid tight seal of the  
opening; and

20 wherein the syringe meets all requirements of the United States Pharmacopoeia  
for sterile water for injection.

24. The syringe of claim 23 wherein the plunger seal is a chlorobutyl based  
elastomer.

25 25. The syringe of claim 24 wherein the norbornene and ethylene copolymer has  
a heat deflection temperature at 0.45 Mpa from about 70°C to about 200°C.

26. The syringe of claim 24 wherein the norbornene and ethylene copolymer has  
a heat deflection temperature at 0.45 Mpa from about 75°C to about 150°.

30

27. The syringe of claim 24 wherein the norbornene and ethylene copolymer has  
a heat deflection temperature at 0.45 Mpa from about 76°C to about 149°C.

28. The syringe of claim 24 wherein the norbornene and ethylene copolymer is capable of being sterilized in an autoclave at 121°C.

29. A method for filling a syringe comprising the steps of:
- 5       providing a syringe body of a norbornene and ethylene copolymer and having an opening;
- sterilizing the syringe body to define a sterilized syringe body;
- transferring the sterilized syringe body to a sterile environment while maintaining the sterility of the sterilized syringe body;
- 
- 10       filling the sterilized syringe body with an appropriate quantity of sterile water for injection;
- sealing the opening with an elastomeric component of a halobutyl based elastomer to define a sterile water for injection syringe; and
- wherein the sterile water for injection syringe meets the requirements of the
- 15       United States Pharmacopoeia for sterile water for injection.

30. The method of claim 29 wherein the norbornene and ethylene copolymer has a heat deflection temperature at 0.45 Mpa from about 70°C to about 200°C.

- 20       31. The method of claim 29 wherein the norbornene and ethylene copolymer has a heat deflection temperature at 0.45 Mpa from about 75°C to about 150°.

32. The method of claim 29 wherein the norbornene and ethylene copolymer has a heat deflection temperature at 0.45 Mpa from about 76°C to about 149°C.

25

33. The method of claim 32 wherein the halobutyl based elastomer is a chlorobutyl-based elastomer.

34. The method of claim 29 wherein the transferring step comprises the step of:
- 30       transferring the sterilized syringe body from a sterilizing station to the sterile environment wherein the sterilized syringe body is exposed to a sterile ambient atmosphere.

35. A method for filling a syringe comprising the steps of:
- providing a syringe body of a norbornene and ethylene copolymer and having an opening;
  - sterilizing the syringe body to define a sterilized syringe body;
  - 5       transferring the sterilized syringe body to a sterile environment while maintaining the sterility of the sterilized syringe body;
  - immediately filling the sterilized syringe body with an appropriate quantity of sterile water for injection;
  - sealing the opening with an elastomeric component of a halobutyl-based elastomer
  - 10   to define a sterile water for injection syringe; and
  - wherein the sterile water for injection syringe meets the requirements of the United States Pharmacopoeia for sterile water for injection.

**ABSTRACT**

A syringe having a syringe body of a norbornene and ethylene copolymer, the body defining a chamber for containing water and having an opening, a plunger seal of a halobutyl-based elastomer sealing the opening; and wherein the syringe meets all  
5 requirements of the United States Pharmacopoeia for sterile water for injection.

---

Fig. 1

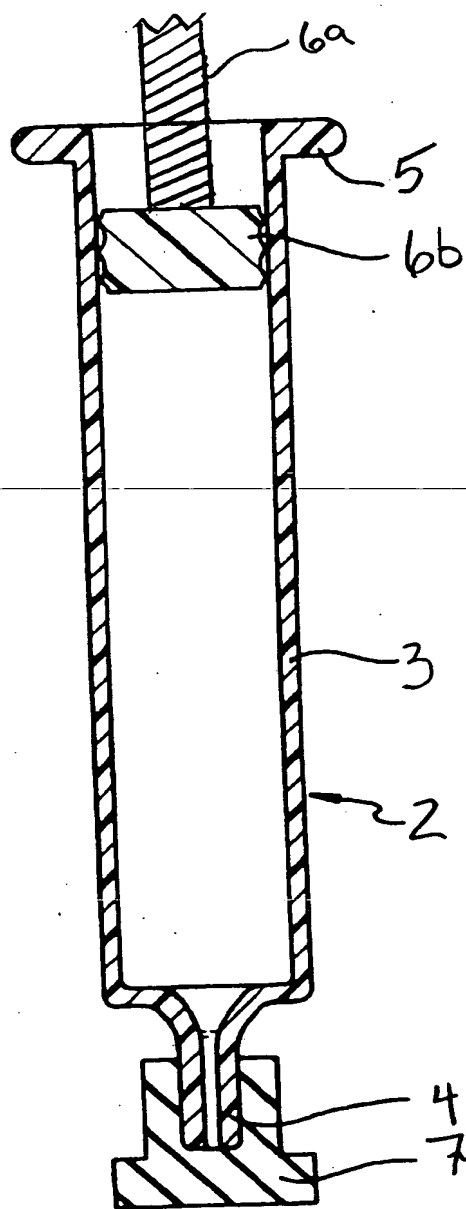


Fig. 2

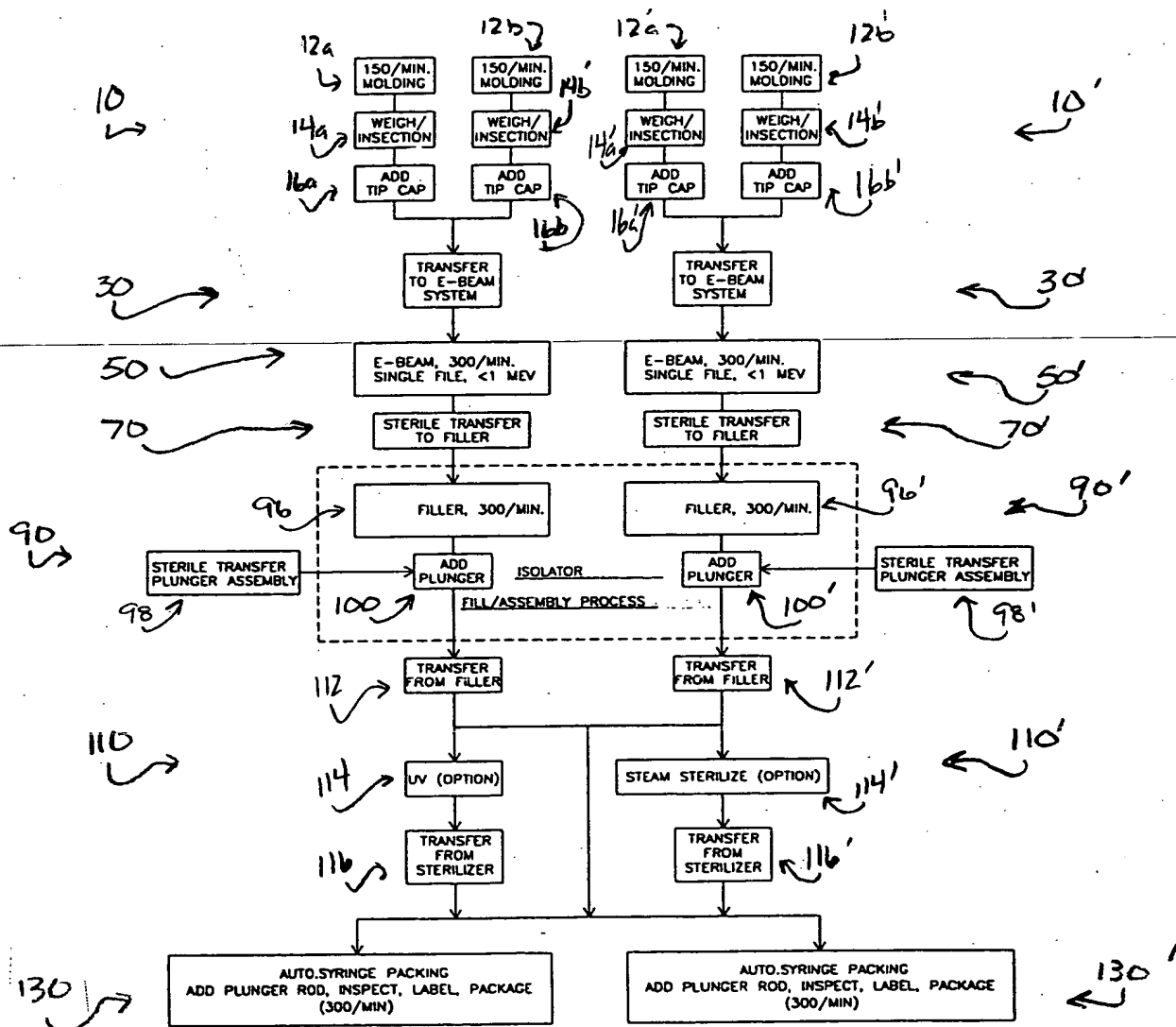


Fig. 3

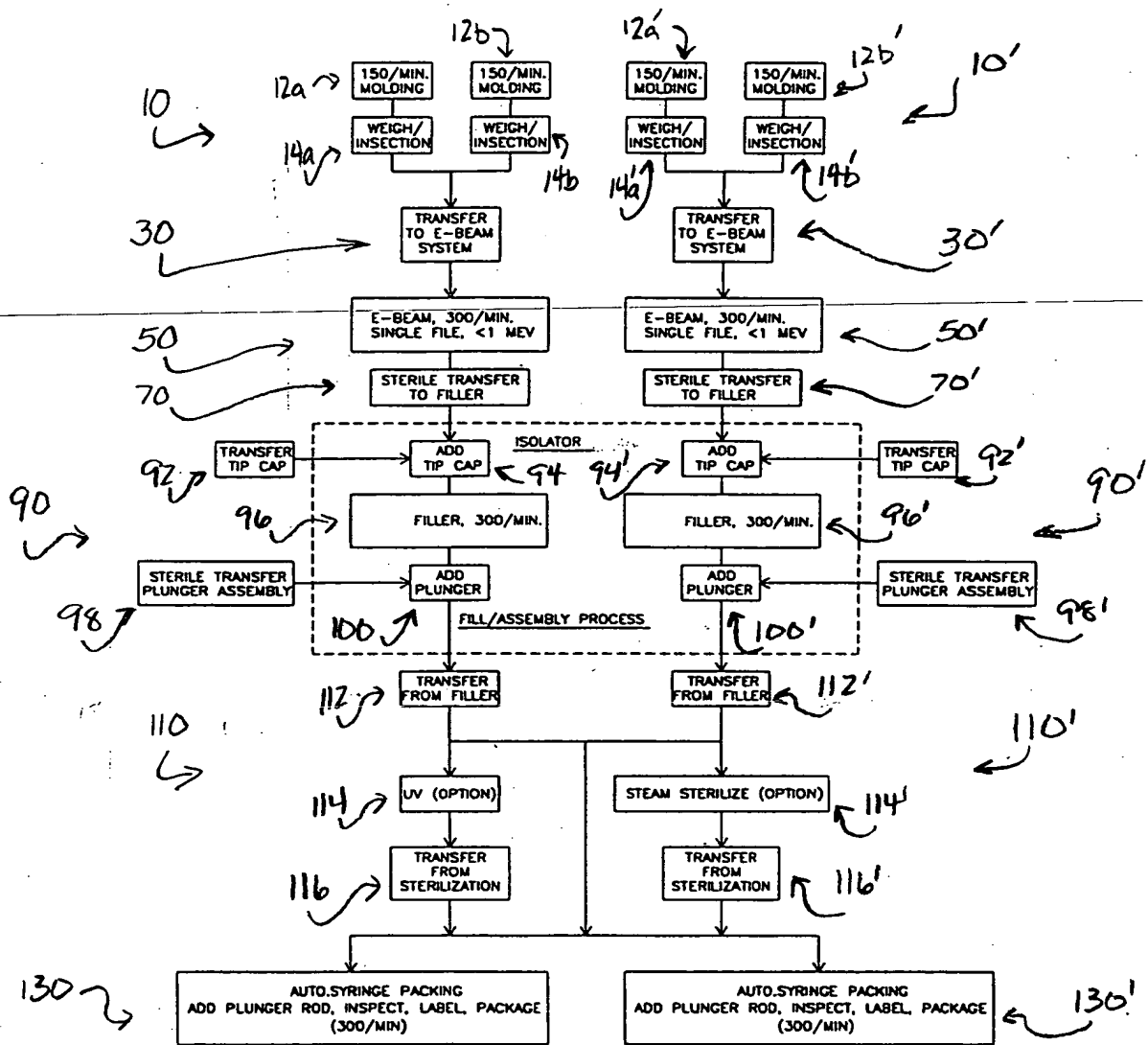


Fig. 4

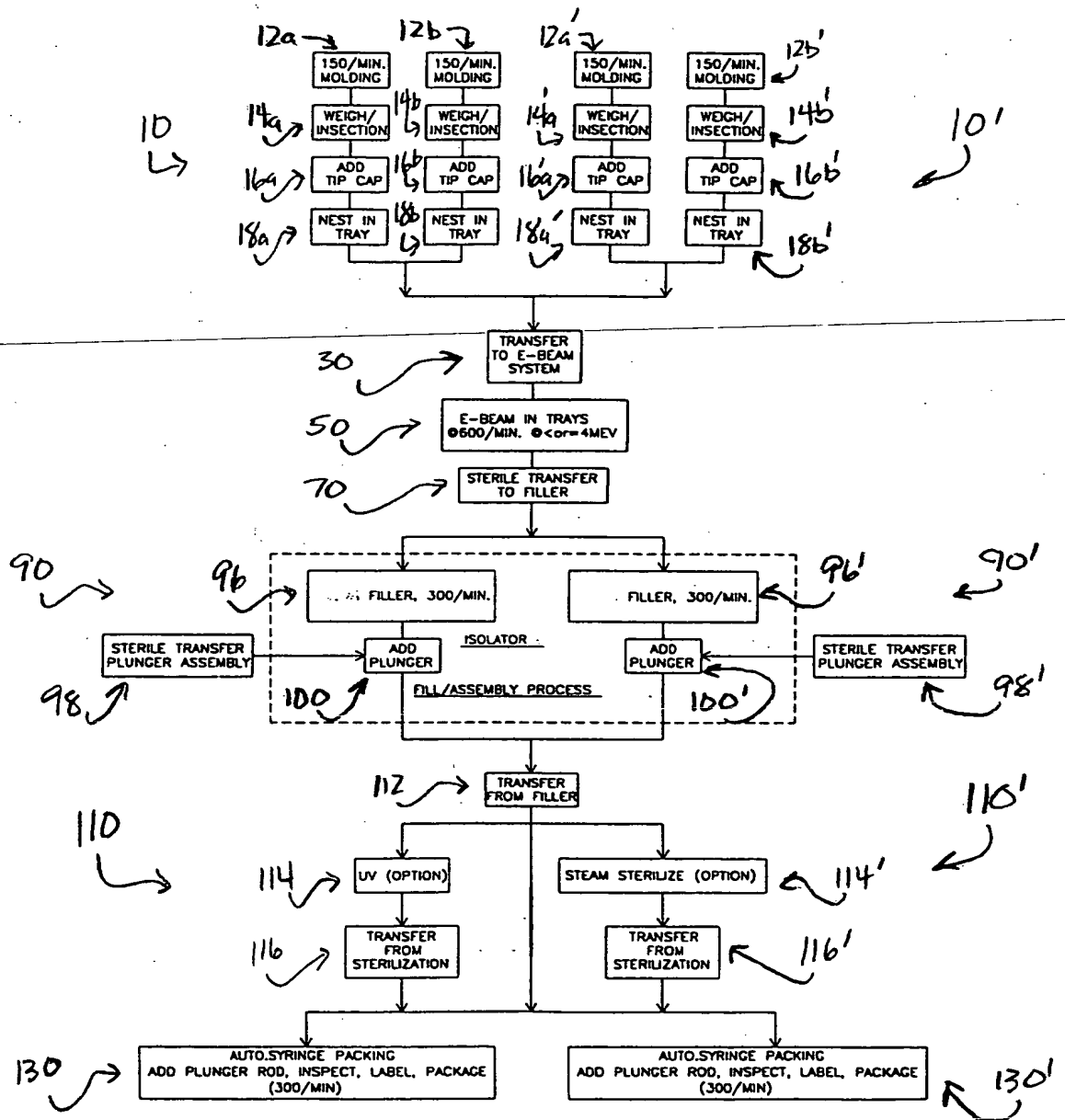
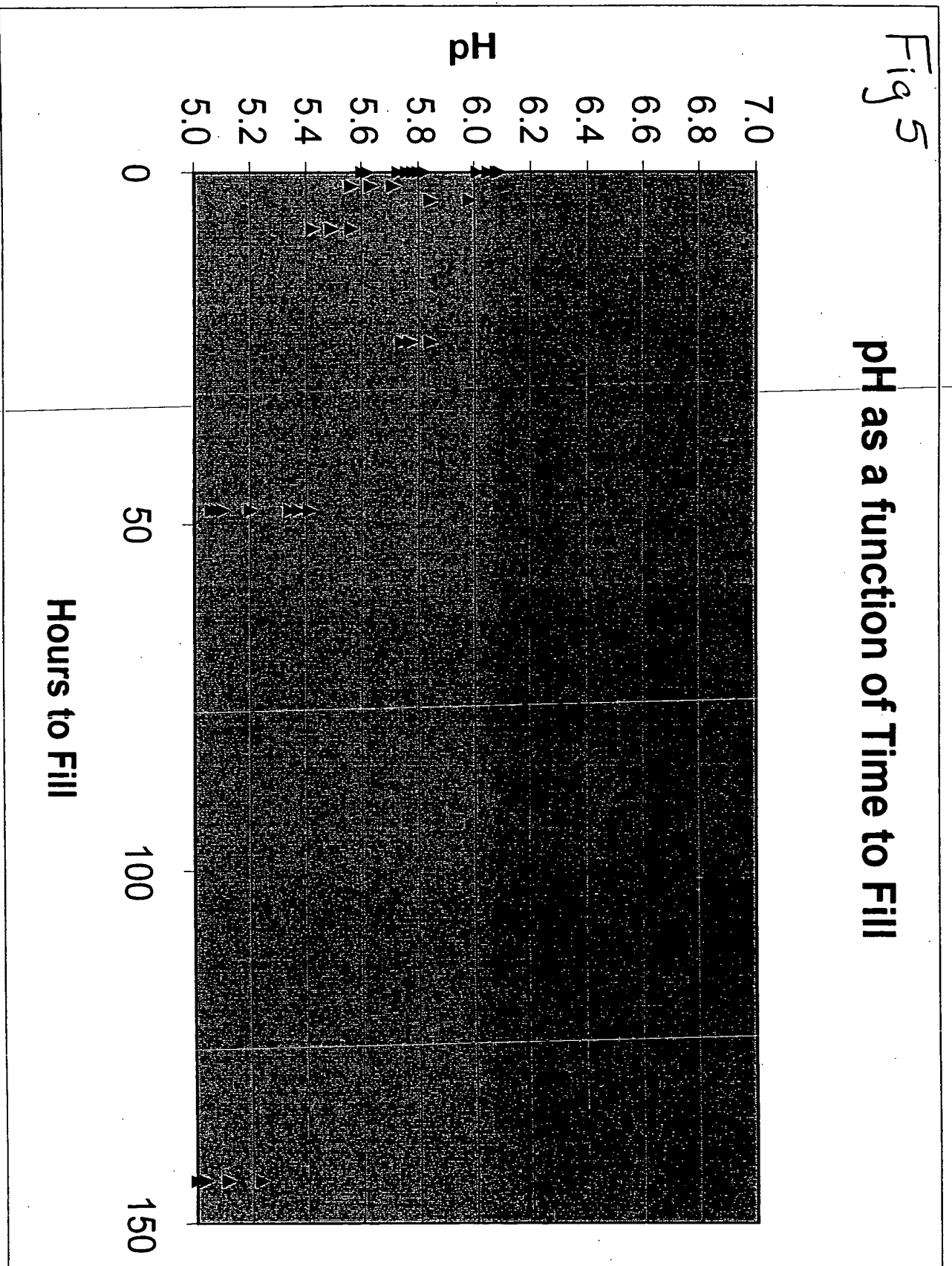


Fig 5

pH as a function of Time to Fill



Date Mailed: June 7, 2001  
Attorney Docket: 1417Y P 552  
Client: Baxter  
Re: Polymeric Syringe and Stopper  
Enclosures:

- Information Disclosure Statement
- PTO Form 1449
- Copies of 182 references
- Return receipt postcard



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Woodworth, et al.

Serial No.: Not Yet Assigned

Filed: March 8, 2001

For: Polymeric Syringe and  
Stopper

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT

U.S. PATENT AND TRADEMARK OFFICE  
COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, Applicants submit herewith Form PTO-1449, "Information Disclosure Statement."

The Examiner is requested to consider carefully the complete text of the enclosed references in connection with the examination of this application. It is requested that the listed references be made of record and included in the "References Cited" portion of any patent issuing from this application.

Since this Statement is being filed before the mailing date of a first Official Action on the merits, no fee is necessary. Please charge any fee associated with this Communication to our Deposit Account No. 23-0280.

Respectfully submitted,

Date: June 7, 2001

By: Peter M. Klobuchar  
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: U.S. Patent and Trademark Office, Commissioner for Patents, Washington, D.C. 20231 on June 7, 2001.

Gerianne M. Flannery  
Gerianne M. Flannery



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**INFORMATION  
DISCLOSURE STATEMENT  
BY APPLICANT  
PTO-1449**

WW&H File No.: 1417Y P 552  
Serial No.: Not Yet Assigned  
Applicant: Woodworth, et al.  
Filing Date: March 8, 2001  
Art Unit: Not Yet Assigned

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#### FOREIGN PATENT DOCUMENTS

Examiner Initial	Publication or Document Number	Date	Country or Patent Office	Translation
	EP 0 563 486 B1	01/01/1901	EPO	No
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	EP 0 839 498 A1	01/01/1901	EPO	No
	EP 0 856 324 A2	01/01/1901	EPO	No

Examiner Initial	Publication or Document Number	Date	Country or Patent Office	Translation
	EP 0 156 464 A1	02/01/85	EPO	No
	EP 0 203 799 B1	08/07/96	EPO	No
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	EP 0 283 164 A2	03/01/88	EPO	No
	EP 0 291 208 A2	11/17/88	EPO	No
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	EP 0 430 585 B1	11/22/90	EPO	No
	EP 0 492 982 B1	12/19/91	EPO	No
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	WO 99/45984	09/16/99	PCT	No
	WO 99/45985	09/16/99	PCT	No

#### OTHER DOCUMENTS

(including Author, Title, Date, Pertinent Pages, etc.)

Examiner Initial	

Date

Examiner: \_\_\_\_\_

Considered: \_\_\_\_\_

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. (123881.1)



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/801,864	03/08/2001	3721	0.00	1417Y P 552	5	35	7

Wallenstein & Wagner, Ltd.  
53rd Floor  
311 S. Wacker Drive  
Chicago, IL 60606-6630

RECEIVED

JUL 10 2001

WALLENSTEIN &amp; WAGNER

CONFIRMATION NO. 6736

## FILING RECEIPT



\*OC000000006261337\*

Date Mailed: 07/05/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Archie Woodworth, Residence Not Provided;  
John Falzone, Residence Not Provided;  
John Darvasi, Residence Not Provided;  
Amy Gillam, Residence Not Provided;  
Jim Kamienski, Residence Not Provided;  
Peggy Barnato, Residence Not Provided;  
Bob Gliniecki, Residence Not Provided;

## Domestic Priority data as claimed by applicant

## Foreign Applications

If Required, Foreign Filing License Granted 07/05/2001

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

## Title

Polymeric syringe body and stopper

TO DOCKETING

**Preliminary Class**

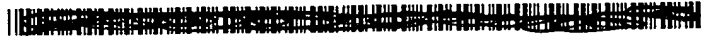
053

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**Data entry by :** TADESSE, ETAGEAN

**Team :** OIPE

**Date:** 07/05/2001



**LICENSE FOR FOREIGN FILING UNDER  
Title 35, United States Code, Section 184  
Title 37, Code of Federal Regulations, 5.11 & 5.15**

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

**PLEASE NOTE the following information about the Filing Receipt:**

- The articles such as "a," "an" and "the" are not included as the first words in the title of an application. They are considered to be unnecessary to the understanding of the title.
- The words "new," "improved," "improvements in" or "relating to" are not included as first words in the title of an application because a patent application, by nature, is a new idea or improvement.
- The title may be truncated if it consists of more than 500 characters (letters and spaces combined).
- The docket number allows a maximum of 25 characters.
- If your application was submitted under 37 CFR 1.10, your filing date should be the "date in" found on the Express Mail label. If there is a discrepancy, you should submit a request for a corrected Filing Receipt along with a copy of the Express Mail label showing the "date in."
- The title is recorded in sentence case.

Any corrections that may need to be done to your Filing Receipt should be directed to:

Assistant Commissioner for Patents  
Office of Initial Patent Examination  
Customer Service Center  
Washington, DC 20231



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/801,864	03/08/2001	Archie Woodworth	1417Y P 552

CONFIRMATION NO. 6736

## FORMALITIES LETTER



\*OC00000006261338\*

Wallenstein & Wagner, Ltd.  
53rd Floor  
311 S. Wacker Drive  
Chicago, IL 60606-6630

Date Mailed: 07/05/2001

## NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

*Filing Date Granted*

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.  
*Applicant must submit \$ 710 to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).*
- Total additional claim fee(s) for this application is \$590.
  - \$270 for 15 total claims over 20.
  - \$320 for 4 independent claims over 3 .
- The oath or declaration is missing.  
*A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- **The balance due by applicant is \$ 1430.**

*A copy of this notice **MUST** be returned with the reply.*

Customer Service Center  
Initial Patent Examination Division (703) 308-1202

PART 1 - ATTORNEY/APPLICANT COPY



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/801,864	03/08/2001	Archie Woodworth	1417Y P 552

CONFIRMATION NO. 6736

## FORMALITIES LETTER



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Wallenstein & Wagner, Ltd.  
53rd Floor  
311 S. Wacker Drive  
Chicago, IL 60606-6630

Date Mailed: 07/05/2001

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FILED UNDER 37 CFR 1.53(b)

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*Applicant must submit \$ 710 to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).*
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- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- The balance due by applicant is \$ 1430.

*A copy of this notice **MUST** be returned with the reply.*

Customer Service Center  
Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

Date Mailed: July 26, 2001  
Attorney Docket: 1417Y P 552  
Client: Baxter  
Re: Polymeric Syringe and Stopper

Enclosures:

- Supplemental Information Disclosure Statement
- PTO Form 1449
- Copies of 3 references
- Return receipt postcard

\_\_\_\_PMK/gmf

PLEASE STAMP & RETURN

Date Mailed: July 26, 2001  
Attorney Docket: 1417Y P 552  
Client: Baxter  
Re: Polymeric Syringe and Stopper  
Enclosures:

- Supplemental Information Disclosure Statement
- PTO Form 1449
- Copies of 3 references
- Return receipt postcard



\_\_\_\_PMK/gmf

PLEASE STAMP & RETURN



Attorney Docket No. 1417Y P 552

**26966**  
PATENT TRADEMARK OFFICE

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

<b>In re Application of:</b>	)	
<b>Woodworth, et al.</b>	)	
	)	<b>Group Art Unit: Not Yet Assigned</b>
<b>Serial No.: 09/801,864</b>	)	
	)	<b>Examiner: Not Yet Assigned</b>
<b>Filed: March 8, 2001</b>	)	
	)	
<b>For: Polymeric Syringe and</b>	)	
<b>Stopper</b>	)	
	)	

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 C.F.R. §§ 1.97 AND 1.98**

Commissioner For Patents  
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, Applicants submit herewith copies of patents, publications or other information of which they are aware that they believe may be material to the examination of this application and, in respect of which, there may be a duty to disclose. These references are listed on appended form PTO-1449. Since this Supplemental Information Disclosure Statement is being filed before the mailing date of a first Official Action on the merits, no fee is necessary.

The filing of this Supplemental Information Disclosure Statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this Supplemental Information Disclosure Statement shall not be construed as an admission against interest in any manner.

The Examiner is requested to carefully consider the complete text of these references in connection with examination of this application.

ATTORNEY DOCKET NO. 1417Y P 516

Serial No.

Page 2

It is requested that the listed references be made of record and included in the "References Cited" portion of any patent issuing from this application.

The Commissioner is hereby authorized to charge any additional fee or credit any overpayment to Deposit Account No. 23-0820.

Respectfully submitted,

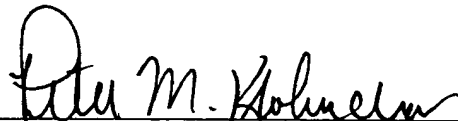
Date: July 26, 2001



26966

PATENT TRADEMARK OFFICE

By:



Peter M. Klobuchar, 43,722

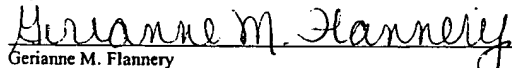
Wallenstein & Wagner, Ltd.

311 S. Wacker Drive, 53rd Floor

Chicago, Illinois 60606-6622

(312) 554-3300

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Commissioner For Patents, Washington, D.C. 20231 on  
July 26, 2001



Gerianne M. Flannery

127233

**INFORMATION  
DISCLOSURE STATEMENT  
BY APPLICANT  
PTO-1449**

WW&H File No.: 1417Y P 552  
Serial No.: 09/801,864  
Applicant: Woodworth, et al.  
Filing Date: March 8, 2001  
Art Unit: Not Yet Assigned

**U.S. PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Name
	5,597,530	01/28/97	Smith, et al.
	6,164,044	12/26/00	Porfano, et al.
	6,250,052 B1	06/26/01	Porfano, et al.

**FOREIGN PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Country	Trans.

Date \_\_\_\_\_

Examiner: \_\_\_\_\_ Considered: \_\_\_\_\_

Examiner: Initial if Citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

127235

Date Mailed: December 4, 2001 (Due: 9/5/01)  
U.S. Application No.: 09/801,864  
Filed: March 8, 2001  
Attorney Docket No.: SFP 5722 (1417YP552 - Baxter)

In Re U.S. Patent Application of Archie Woodworth, et al. for POLYMERIC SYRINGE BODY AND STOPPER; Examiner: Unassigned; Group Art Unit: 3721.

Enclosures:

- Response to Notice of Missing Parts (original + 1 copy);
- Check in the amount of \$1,476.00;
- Executed Declaration and Power of Attorney;
- Petition for Three Month Extension of Time;
- Check in the amount of \$920.00 for the extension fee;
- Copy of Notice to File Missing Parts; and
- Return Receipt Postcard



Received

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(135960.1) MJG/sjg

Date Mailed: December 4, 2001 (Due: 9/5/01)  
U.S. Application No.: 09/801,864  
Filed: March 8, 2001  
Attorney Docket No.: SFP 5722 (1417YP552 - Baxter)

In Re U.S. Patent Application of Archie Woodworth, et al. for POLYMERIC SYRINGE BODY AND  
STOPPER; Examiner: Unassigned; Group Art. Unit: 3721.

---

Enclosures:

- Response to Notice of Missing Parts (original + 1 copy);
- Check in the amount of \$1,476.00;
- Executed Declaration and Power of Attorney;
- Petition for Three Month Extension of Time;
- Check in the amount of \$920.00 for the extension fee;
- Copy of Notice to File Missing Parts; and,
- Return Receipt Postcard

Received \_\_\_\_\_ (135960.1) MJG/sjg  
PLEASE STAMP AND RETURN

**In Re U.S. Patent Application Of:**

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)  
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)

) Group Art Unit: 3721

)

) Examiner: Unassigned

)

)

)

1. Check in the amount of \$1,476.00 for the filing fee for this application and the surcharge for the late filing of the Declaration and Power of Attorney;
2. Executed Declaration and Power of Attorney;
3. Petition for Three Month Extension of Time;
4. Check in the amount of \$920.00 for the Petition fee; and,
5. Copy of Notice to File Missing Parts of Nonprovisional Application.

U.S. Application No. 09/801,864  
Filed: March 8, 2001  
Response to Notice of Missing Parts

Page 2

You are hereby authorized to **debit any payment deficiencies or credit any overpayments** only with regard to the above-identified Application to our Deposit Account No. 23-0280. A duplicate copy of this sheet is attached.

Respectfully submitted,

Dated: December 4, 2001

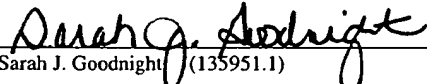
By: 

Matthew J. Gryzlo, Reg. No. 43,648  
WALLENSTEIN & WAGNER, LTD.  
311 South Wacker Drive - 53rd Floor  
Chicago, Illinois 60606-6622  
(312) 554-3300

---

**CERTIFICATE OF MAILING (37 C.F.R. § 1.8a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: BOX MISSING PARTS, Commissioner of Patents, Washington, D.C. 20231 on December 4, 2001.

  
Sarah J. Goodnight (135951.1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re U.S. Patent Application Of: )  
ARCHIE WOODWORTH, JOHN FALZONE, )  
JOHN DARVASI, AMY W. GILLUM, JAMES )  
KAMIENSKI, MARGARET J. BARNATO, )  
ROBERT GLINIECKI, NEERVALUR V. )  
RAGHAVAN, CRAIG SANDFORD, and )  
DEBORAH McCLELLAND )

Application No. 09/801,864 ) Group Art Unit: 3721

Filed: March 8, 2001 ) Examiner: Unassigned

For: POLYMERIC SYRINGE BODY AND )  
STOPPER )

**PETITION FOR THREE-MONTH EXTENSION OF TIME  
PURSUANT TO 37 C.F.R. § 1.136(a)**

BOX MISSING PARTS  
Commissioner for Patents  
Washington, D.C. 20231

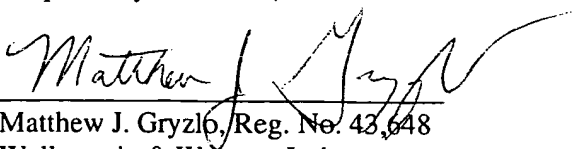
Dear Sir:

Applicants in the above-identified Application request a three (3) month extension of time in which to respond to the Notice to File Missing Parts dated July 5, 2001. The period of time to respond was set to expire on September 5, 2001. With this Extension, the time to respond is now set at December 5, 2001. Applicants submit herewith a check in the amount of \$920.00 for the three month extension fee.

You are hereby authorized to debit or credit our Account No. 23-0280 for any payment deficiencies or overpayments with regard to this matter.

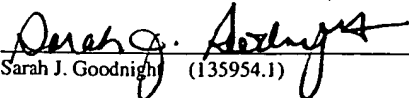
Respectfully submitted,

Dated: December 4, 2001

By:   
Matthew J. Gryzl, Reg. No. 43,648  
Wallenstein & Wagner, Ltd.  
311 South Wacker Drive, 53<sup>rd</sup> Floor  
Chicago, IL 60606-6622  
(312) 554-3300

**CERTIFICATE OF MAILING (37 C.F.R. § 1.8a)**

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Sarah J. Goodnight (135954.1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**DECLARATION AND POWER OF ATTORNEY**

As named inventors, **Archie Woodworth, John Falzone, John Darvasi, Amy W. Gillum, James Kamienski, Margaret J. Barnato, Robert Gliniecki, Neervalur V. Raghavan, Craig Sandford, and Deborah McClelland**, and we hereby declare that:

Our residences, post office addresses and citizenships are as stated below next to our names.

We believe we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled "**POLYMERIC SYRINGE BODY AND STOPPER**", the Specification of which was filed on March 8, 2001 as United States Application Number 09/801,864.

We hereby state that we have reviewed and understand the contents of the above-identified Specification, including the Claims, as amended by any Amendment referred to above.

We acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56.

We hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the Application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
<u>NONE</u> Number	<u>Country</u>	<u>Day/Month/Year Filed</u>	<u>Yes</u>	<u>No</u>

We hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

<u>NONE</u> Application Number	<u>Filing Date</u>
-----------------------------------	--------------------

We hereby claim the benefit under 35 U.S.C. § 120 of any United States Application(s),

or § 365(c) of any PCT International Application designating the United States, listed below and, insofar as the subject matter of each of the Claims of this Application is not disclosed in the prior United States or PCT International Application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior Application and the national or PCT international filing date of this Application:

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Application Number	Filing Date	Status
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We hereby appoint the following attorney(s) and/or agent(s) to prosecute this Application and transact all business in the Patent and Trademark Office connected therewith.

Francis C.M. Kowalik	- 34,646	Daniel N. Christus	- 29,626	Edward L. Bishop	- 39,110
Mark J. Buonaiuto	-31,593	Linda A. Kuczma	- 30,861	James P. Muraff	- 39,785
Joseph J. Barrett	-34,769	Roger H. Stein	- 31,882	Austin J. Foley	- 42,543
Janice Guthrie	-35,170	Thomas K. Stine	- 32,310	Matthew J. Gryzlo	- 43,648
Charles R. Mattenson	-30,660	Micheal D. Lake	- 33,727	Peter M. Klobuchar	- 43,722
Paula J Kelly	-37,624	Joseph A. Fuchs	- 34,604	Brent A. Hawkins	- 44,146
Jeffrey C. Nichols	-36,879	Robert W. Diehl	- 35,118	William J. Lenz	- 44,208
Bradford R.L. Price	-29,101	Bradley F. Rademaker	- 35,331	Joseph M. Kinsella Jr.	- 45,743
		Richard C. Himelhoch	- 35,544	Stephen R. Auten	-47,396
		Monique A. Morneault	- 37,893		
		Jeffrey R Gargano	- 38,148		
		Paul J. Nykaza	- 38,984		

Send correspondence and direct telephone calls to:

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**ASSISTANT GENERAL COUNSEL**  
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**ONE BAXTER PARKWAY, DF3-2E**  
**DEERFIELD, ILLINOIS 60015**  
**847/948.2000 (Phone)**

We hereby declare all statements made herein of our own knowledge are true and all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issued thereon.

Full Name of First Joint Inventor: **Archie Woodworth**

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Date: *30 October 2001*

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Citizenship: **U.S.A.**

Mailing Address: **Same as above.**

Inventor's Signature: *John Falzone*

Date: *10/29/01*

Full Name of Third Joint Inventor: **John Darvasi**

Residential Street Address: **28 Lynn Drive**

City and State/Province: **Hawthorn Wood, IL**

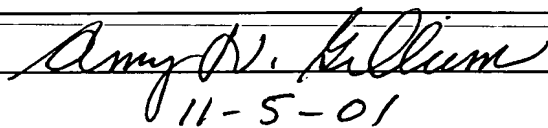
Country and Zip/Postal Code: **U.S.A. 60047**

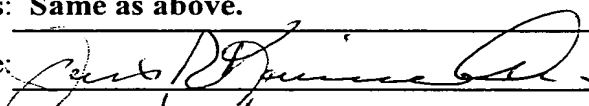
Citizenship: **U.S.A.**

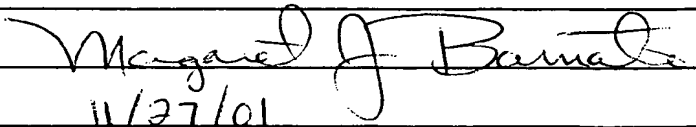
Mailing Address: **Same as above.**

Inventor's Signature: *John Darvasi*

Date: *11/16/01*

Full Name of Fourth Joint Inventor: <sup>W. Aut 11-5-01</sup> **Amy N. Gillum**  
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Inventor's Signature:   
Date: **11-5-01**

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Inventor's Signature:   
Date: **11/06/01**

Full Name of Sixth Joint Inventor: **Margaret J. Barnato**  
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Citizenship: **U.S.A.**  
Mailing Address: **Same as above.**  
Inventor's Signature:   
Date: **11/27/01**

Attorney Docket No. 1417Y P 552  
Baxter Ref: SFP 5772

- 5 -

PATENT

Full Name of Seventh Joint Inventor: **Robert Gliniecki**

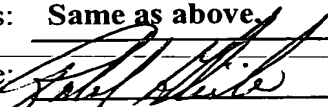
Residential Street Address: **9604 Fox Trail**

City and State/Province: **Spring Grove, IL**

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Citizenship: **U.S.A.**

Mailing Address: **Same as above.**

Inventor's Signature: 

Date: 

Full Name of Eighth Joint Inventor: **Neervalur V. Raghavan**

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Citizenship: **U.S.A.**

Mailing Address: **Same as above.**

Inventor's Signature: *Neervalur V. Raghavan*

Date: *12/4/01*

Full Name of Ninth Joint Inventor: **Craig Sandford**

Residential Street Address: **751 Dunhill Drive**

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Citizenship: **U.S.A.**

Mailing Address: **Same as above.**

Inventor's Signature: *Craig Sandford*

Date: *12/4/01*

Full Name of Tenth Joint Inventor: **Deborah McClelland**

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Citizenship: **U.S.A.**

Mailing Address: **Same as above.**

Inventor's Signature: *Deborah J. McClelland*

Date: *12/4/01*

Date Mailed: February 26, 2002  
U.S. Application No.: 09/801,864  
Filed: March 8, 2001  
Attorney Docket No.: SFP 5722 (1417YP552 - Baxter)

---

In Re U.S. Patent Application of Archie Woodworth, et al. for POLYMERIC SYRINGE BODY AND STOPPER; Examiner: Unassigned; Group Art Unit: 3721.

Enclosures:

- Supplemental Information Disclosure Statement;
- PTO Form 1449, together with a copy of each reference listed thereon; and,
- Return Receipt Postcard

Received \_\_\_\_\_ (141631.1) MJG/sjg  
PLEASE STAMP AND RETURN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re U.S. Patent Application Of: )  
ARCHIE WOODWORTH, et al. )  
Application No. 09/801,864 ) Group Art Unit: 3721  
Filed: March 8, 2001 ) Examiner: Unassigned  
For: POLYMERIC SYRINGE BODY AND )  
STOPPER )

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, Applicants submit herewith Form PTO-1449, "Supplemental Information Disclosure Statement," and a copy of each reference listed therein.

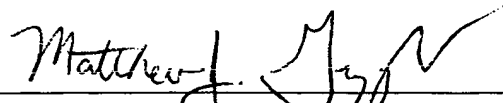
The Examiner is requested to consider carefully the complete text of the enclosed references in connection with the examination of this application. It is requested that the listed references be made of record and included in the "References Cited" portion of any patent issuing from this application.

Since this Statement is being filed before the mailing date of a first Official Action on the merits, no fee is necessary. Please charge any fee associated with this Communication to our Deposit Account No. 23-0280.

Respectfully submitted,

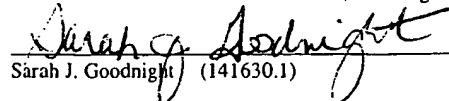
Date: February 26, 2002

By:

  
Matthew J. Gryzlo, Reg. No. 43,648  
Wallenstein & Wagner, Ltd.  
311 S. Wacker Drive, 53rd Floor  
Chicago, Illinois 60606-6622  
(312) 554-3300

**CERTIFICATE OF MAILING (37 C.F.R. § 1.8a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231 on February 26, 2002.

  
Sarah J. Goodnight (141630.1)

**SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT**

*(Use several sheets if necessary)*

**Docket Number (Optional)**

1417Y P 552 (SFP-5772)

**Application Number**

09/801,864

**Applicant(s)**

Archie Woodworth, et al.

**Filing Date**

March 8, 2001

**Group Art Unit**

3721

**U.S. PATENT DOCUMENTS**

*EXAMINER- INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		2,856,923	10/21/1958	Roger, et al.			
		4,202,334	05/13/1980	Elson			
		4,718,463	01/12/1988	Jurgens, Jr., et al.			
		4,998,922	03/12/1991	Kuracina, et al.			
		5,092,852	03/03/1992	Poling			
		5,141,430	08/25/1992	Maus, et al.			
		5,197,953	03/30/1993	Colonna			
		5,256,154	10/26/1993	Liebert, et al.			
		5,373,684	12/20/1994	Vacca			
		5,399,163	03/21/1995	Peterson, et al.			
		5,519,984	05/28/1996	Beussink, et al.			
		5,531,255	07/02/1996	Vacca			
		5,624,402	04/29/1997	Imbert			
		5,687,542	11/18/1997	Lawecki, et al.			
		5,785,691	07/28/1998	Vetter, et al.			
		5,891,086	04/06/1999	Weston			
		6,096,002	08/01/2000	Landau			
		6,190,364 B1	02/20/2001	Imbert			
		6,196,998 B1	03/06/2001	Jansen, et al.			

**FOREIGN PATENT DOCUMENTS**

	REF	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
		EP 0 227 401 A2	01.07.1987	EPO				
		EP 0 553 926 A1	04.08.1993	EPO				
		EP 0 555 900 A1	18.08.1993	EPO				
		EP 0 741 080 A1	06.11.1996	EPO				
		EP 0 815 884 A1	07.01.1998	EPO				
		EP 0 849 173 A1	24.06.1998	EPO				X
		WO 94/13328	23.06.1994	PCT				
		WO 94/13345	23.06.1994	PCT				
		WO 95/12482	11.05.1995	PCT				
		WO 96/13289	09.05.1996	PCT				X

<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	<b>Docket Number (Option)</b> 1417Y P 552 (SFP-5772)	<b>Application Number</b> 09/801,864
	<b>Applicant(s)</b> Archie Woodworth, et al.	
	<b>Filing Date</b> March 8, 2001	<b>Group Art Unit</b> 3721

	REF	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
		WO 96/18541	20.06.1996	PCT				
		WO 96/28201	19.09.1996	PCT				X
		WO 97/44068	27.11.1997	PCT				X
		WO 98/05366	12.02.1998	PCT				X
		WO 98/19715	14.05.1998	PCT				X
		WO 98/33705	06.08.1998	PCT				
		WO 00/35520	22.06.2000	PCT				
<b>OTHER DOCUMENTS</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>								
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>				
<b>EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

FORM PTO-A820  
(also form PTO-1449)

(141533.1)



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO.	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/801,864	03/08/2001	3721	1476	SFP 5772 (1417Y P552)	5	35	7

Wallenstein & Wagner, Ltd.  
53rd Floor  
311 S. Wacker Drive  
Chicago, IL 60606-6630

# TO DOCKETING

CONFIRMATION NO. 6736

UPDATED FILING RECEIPT



\*OC000000008018091\*

Date Mailed: 05/03/2002

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

**Applicant(s)**

Archie Woodworth, Barrington, IL;  
John Falzone, Crystal Lake, IL;  
John Darvasi, Hawthorn Wood, IL;  
Amy W. Gillum, Lake Villa, IL;  
James Kamienski, Chicago, IL;  
Margaret J. Barnato, Lake Forest, IL;  
Robert Gliniecki, Spring Grove, IL;  
Neervalur V. Raghavan, Northbrook, IL;  
Craig Sandford, Buffalo Grove, IL;  
Deborah McClelland, Lake Villa, IL;

Domestic Priority data as claimed by applicant

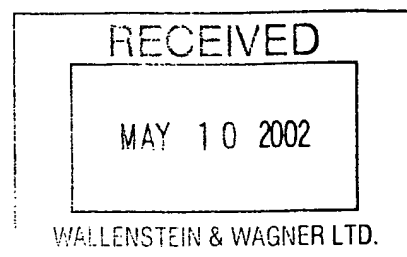
Foreign Applications

If Required, Foreign Filing License Granted 07/05/2001

Projected Publication Date: 09/12/2002

Non-Publication Request: No

Early Publication Request: No



**Title**

Polymeric syringe body and stopper

**Preliminary Class**

053

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**LICENSE FOR FOREIGN FILING UNDER  
Title 35, United States Code, Section 184  
Title 37, Code of Federal Regulations, 5.11 & 5.15**

---

**GRANTED**

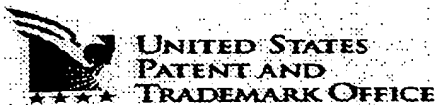
The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



Commissioner for Patents  
Washington, DC 20231  
www.uspto.gov

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/801,864	03/08/2001	Archie Woodworth	SFP 5772 (1417Y P552)

CONFIRMATION NO. 6736

Wallenstein & Wagner, Ltd.  
53rd Floor  
311 S. Wacker Drive  
Chicago, IL 60606-6630



\*OC000000008893792\*

Title: Polymeric syringe body and stopper

Publication No. US-2002-0139088-A1

Publication Date: 10/03/2002

Date Mailed: 10/03/2002

### NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at [www.uspto.gov](http://www.uspto.gov). The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Crystal Gateway 4, Room 335, Washington, D.C. 20231, or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at [www.uspto.gov](http://www.uspto.gov) using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at (703) 305-3028.

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Initial Patent Examination Division (703) 308-1202

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# UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,864	03/08/2001	Archie Woodworth	SFP 5772 (1417Y P552)	6736

7590 05/07/2003

Wallenstein & Wagner, Ltd.  
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Chicago, IL 60606-6630

EXAMINER

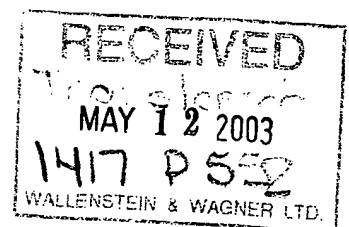
ART UNIT

PAPER NUMBER

3721

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.





# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

## NOTICE UNDER 37 CFR 1.251 - Pending Application

☒ The file of the above-identified application cannot be located after a reasonable search. Therefore, the Office is initiating the reconstruction of the file of the above-identified application pursuant to the provisions of 37 CFR 1.251.

Applicant is given a period of **THREE (3) MONTHS** from the mailing date of this notice within which to provide a copy of applicant's record (if any) of all of the correspondence between the Office and applicant for the above-identified application (except for U.S. patent documents), a list of such correspondence, and a statement that the copy is a complete and accurate copy of applicant's record of all of the correspondence between the Office and the applicant for the above-identified application (except for U.S. patent documents), and whether applicant is aware of any correspondence between the Office and applicant for the above-identified application that is not among applicant's records.

☐ The following paper(s) pertaining to the above-identified application cannot be located after a reasonable search:

Therefore, the Office is initiating the reconstruction of such paper(s) pursuant to the provisions of 37 CFR 1.251.

Applicant is given a period of **THREE (3) MONTHS** from the mailing date of this notice within which to provide a copy of the paper(s) listed above and a statement that the copy of such paper(s) is a complete and accurate copy of applicant's record of such paper(s).

Alternatively, applicant may reply to this notice by producing applicant's record (if any) of all of the correspondence between the Office and the applicant for the above-identified application for the Office to copy (except for U.S. patent documents), and provide a statement that the papers produced by applicant are applicant's complete record of all of the correspondence between the Office and the applicant for the above-identified application (except for U.S. patent documents), whether applicant is aware of any correspondence between the Office and the applicant for the above-identified application that is not among applicant's records. Such records must be brought to the Customer Service Center in the Office of Initial Patent Examination (Crystal Plaza 2, 2011 South Clark Place, Arlington, VA 22202).

If applicant does not possess any record of the correspondence between the Office and the applicant for the above-identified application (or any copy of the paper(s) listed above), applicant must reply to this notice by providing a statement that applicant does not possess any record of the correspondence between the Office and the applicant for the above-identified application.

Failure to reply to this notice in a timely manner will result in abandonment of the above-identified application. The three-month period for reply to this notice may be extended (up to a maximum of six months) under the provisions of 37 CFR 1.136(a). However, failure to reply within this three-month period will result in a reduction of any patent term adjustment. See 37 CFR 1.704(b).

☒ A printout from PALM of the contents of the file of the above-identified application is included with this notice.  
Direct the reply to this notice to:

Box Reconstruction  
United States Patent and Trademark Office  
Washington, DC 20231

Direct questions concerning this notice to:

*Carolyn Brown*  
(703) 308-2192

FAX 703 - 872 9301

*Attention Carolyn Brown*

FORM PTO-2053-B (REV. 11/2000)

Approved for use through xx/xx/xxxx. OMB 0651-0031

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In re Application of: \_\_\_\_\_

Application No.: \_\_\_\_\_

Filing Date: \_\_\_\_\_

Title: \_\_\_\_\_

**Carolyn Brown**  
**Supervisory Legal Instrument Exam**  
**Group 3700**

Direct to:

Box Reconstruction  
United States Patent and Trademark Office  
Washington, DC 20231

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*Attention Carolyn Brown*

FORM PTO-2053-B (REV. 11/2000)

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